hygh-tec.

hygh-tec® Fecal Management System

Material and Design Overview

amb advanced medical balloons

HYGH-TEC® STOOL FECAL MANAGEMENT SYSTEM

Introduction

Fecal management remains a significant challenge in critical care settings, with stool leakage compromising patient dignity, safety, and clinical outcomes. Advanced Medical Balloons' hygh-tec Fecal Management System addresses this issue, leveraging innovative materials and design to minimize leakage and enhance patient care.

Even though the 1st generation products, which were introduced approx. 20 years ago, reduced stool leakage in ICUs, clinicians still reported notably high leakage rates[1].

Advanced Medical Balloons' second-generation FMS addresses this challenge with innovative materials and design enhancements, significantly minimizing leakage and its associated complications and costs. The system's breakthrough lies in its reimagined catheter balloon/shaft, German engineered to create a secure, trans-anal canal seal that aligns with the colon's natural movements and functions.

The key to unlocking superior outcomes was understanding and reimagining the material and shape of the catheter balloon to create a true, trans anal canal seal that aligns with the natural functions/movement of the colon.

By reducing stool leakage, there is a concomitant reduction in potential complications and relevant associated costs in time, labor and materials in cleaning

Product Overview

This innovative design represents a significant advancement in stool drainage systems, offering improved outcomes for both healthcare providers and patients through its adaptive technology and patient-centered design.

1. Hygh-tec Key Material and Designs

Feature	hygh-tec® basic-plus	1st Generation Systems
1. Material	Polyurethane (PUR)	Silicone
2. Balloon Shape	Dumb-bell design	Oval or Cylindrical design
3. Balloon Fill	Air	Water
4. Weight of Balloon	Lighter (air-filled) 8 Grams	Heavier (water-filled) 43 Grams
5. Sealing Mechanism	Dynamic, self-adjusting	Static
6. Internal Shaft Design	Corrugated, adaptive, resists twisting	Flimsy, easily twisted, easily migrates

2. Balloon / Tubing Material - The Polyurethane Advantage

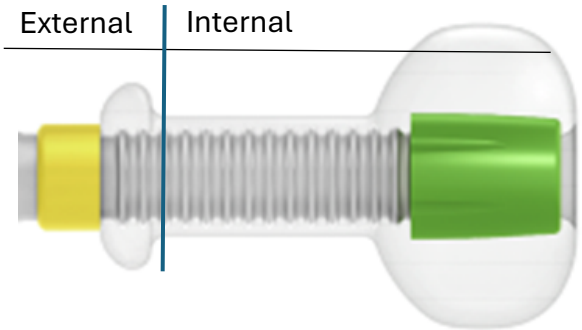
The hygh-tec® basic-plus uses medical-grade polyurethane (PUR) with specific properties that make it ideal for this application:

Can be processed into microscopically thin-walled balloon structures	*Thin-walled structures allow long-term placement of a catheter with the **smallest possible force on adjacent rectal tissue***
Withstands high mechanical loads even in the low wall thickness range and **remains dimensionally stable**	***Can advantageously replace PVC & silicone in FMS catheter technologies*** *and allow catheter designs previously not possible*
Balloon components are flexibly conforming at the smallest applied force and return to their original shape without delay when the applied force decreases	*Enables novel functionalities that **dynamically adapt to the respective organ** through the combination of shape and micro-thin wall thickness*
Shore Hardness of 95A	*At a 95A level, the balloon material **is firm enough to maintain it's shape** yet soft and flexible to move with the body*

- **Compared to Traditional Silicone**:
    - More durable: Better resistance to wear and tear
    - More stable: Maintains intended shape over time
    - More responsive: Better at returning to original shape after movement

3. Hygh-tec Balloon Shape

- Dumbbell-Shaped: The balloon has a unique, dumbbell-like shape with bulbous ends and a narrower central section.
- Asymmetrical Design: The balloon's shape adapts to the natural contours of the anal canal.



The hygh-tec balloon is specifically molded during production to achieve a dumbbell shape that serves multiple purposes:

- **Dynamic Sealing Mechanism**
  - Shape of polyurethane shaft designed to easily move with sphincter muscles
  - Dumbbell Shape creates two responsive sealing zones
  - Adapts to anatomical changes
- **Mechanical Retention**
  - Internal (proximal) and External (distal) sealing ends prevent device migration
  - Creates natural lightweight sealing points
  - Maintains stable position during use
- **Air-Filled**
  - Uses air instead of water
  - Creates a "tension-less" state when positioned
  - Responds to natural body movements
  - Significantly lighter than water-filled alternatives

4.Shore Hardness of 95a

A Key Innovation in Balloon Design & Why It Matters for Patient Care

- **Understanding Shore Hardness**
  - Think of Shore hardness like the "memory" of a material - how well it maintains its intended shape while still being flexible:
- **Scale**: Measured from 0 (very soft) to 100 (very firm) on the Shore A scale
- **hygh-tec® basic-plus**: Uses polyurethane with Shore 95A hardness
  - Firm enough to resist unwanted expansion
  - Flexible enough for comfort
  - Returns reliably to its molded shape

The Bottom Line

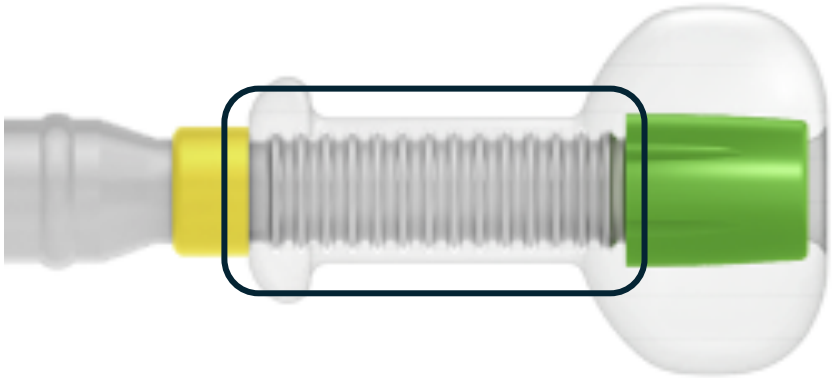
Shore hardness of 95A in the polyurethane balloon is like having a "smart" balloon that:

- Stays light (air-filled)
- Keeps its shape (does not allow sustained over-fill or overstretch)
- Moves naturally with the patient
- Maintains proper positioning
- Provides reliable sealing

This creates a significant improvement over traditional water-filled balloons, offering better control, improved comfort, and enhanced safety for patients.

5. Stool Draining Internal Corrugated Shaft

The corrugated (wave-shaped) shaft represents the integration of material properties and design:

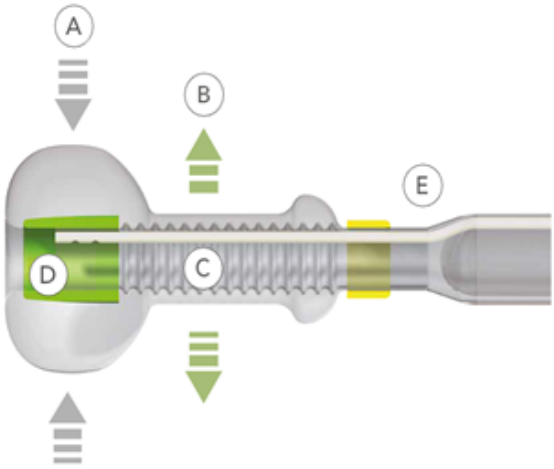


- **Structure and Function**:
  - Wave-like rings and valleys in the shaft
  - Made possible by specific polyurethane properties
  - Engineered to work with sphincter muscles
  - Resists kinking or twisting
- **How It Works**:
  - When sphincter muscle tone is normal:
    - Shaft contracts radially
    - Maintains position and seal
    - Adapts to pressure
  - When sphincter relaxes:
    - Shaft straightens
    - Opens drainage pathway for stool
    - Maintains position and seal
- **Integration with Balloon**:
  - Connects to dumbbell balloon
  - Creates seamless transition
  - Maintains consistent internal diameter for drainage

6. How These Features Work Together

The Synergy of Design

Advanced Engineering in Action



A – intra-rectal anchoring balloon segment
B – trans-anal sealing balloon segment
C – Internal stool draining tube/shaft
D – Olive gel ring stabilizes drainage access
E – Yellow gel ring for positioning accuracy

1. **Material Enables Design**:
    - Polyurethane's specific properties allow:
        - Precise molding of dumbbell shape
        - Creation of functional corrugated shaft
        - Consistent performance over time
2. **Shape Enables Function**:
    - Dumbbell shape creates:
        - Natural anchoring points
        - Optimal sealing zones
        - Stable positioning
3. **Corrugated Shaft Enables Performance**:
    - Wave design provides:
        - Automatic adaptation to movement
        - Efficient drainage comfortable fit

Real-World Impact of Design

1st Generation Water-Filled Balloon	hygh-tec® Air-Filled PUR Balloon
Heavy weight pulls down	Lightweight, minimal pull
Can stretch unpredictably	Maintains molded shape
Needs frequent adjustments	Stays in proper position
Variable pressure on tissues	Consistent, controlled pressure

Summary

The hygh-tec® basic-plus features a revolutionary polyurethane dumb-bell shaped balloon and wave-shaped internal shaft that rapidly adapt to patient anatomy:

- **Self-Adjusting Design**: Contracts when sphincter contracts, straightens when relaxed
- **Intelligent Drainage**: Automatically opens drainage pathways as needed
- **Dynamic Sealing**: Maintains seal integrity while adapting to patient movement
- **Reduced Tissue Pressure**: Flexible weightless design minimizes risk of pressure-related injuries

This combination of advanced materials, innovative shape design, and mechanical engineering creates a system that significantly improves upon 1st generation devices. The synergy between these features results in better outcomes for both patients and healthcare providers.

ADDENDUM

Hygh-tec Synchronization Explained

Recto-Anal Compartment: Figure 1

- absorbs the current force in the rectum (A) and uses it synchronously to seal the sphincter (B)
- adapts to the current pressure situation in the rectum and abdomen
- reliable trans-anal seal even with watery thin stools
- Trans-anal sealing even in vigilant and mobilized patients

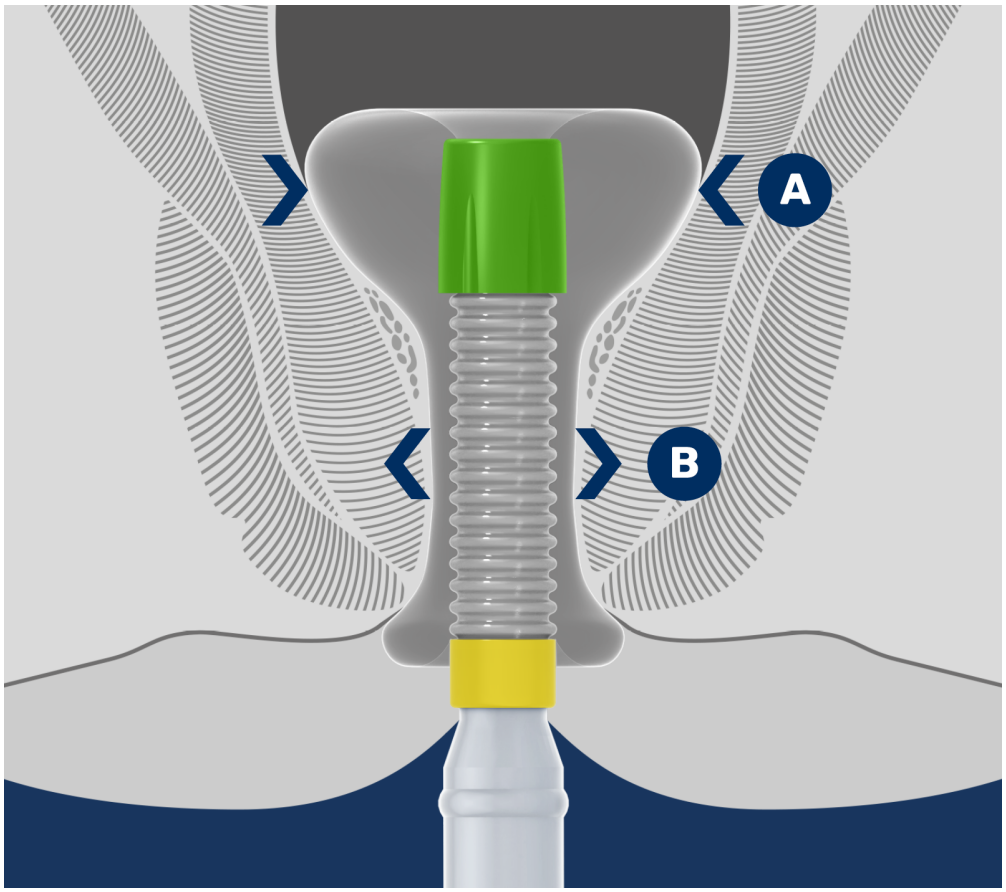


Figure 1: Recto-Anal Compartment

IAS-EAS Contraction - Figure 2

Flexibly conforming and adaptable

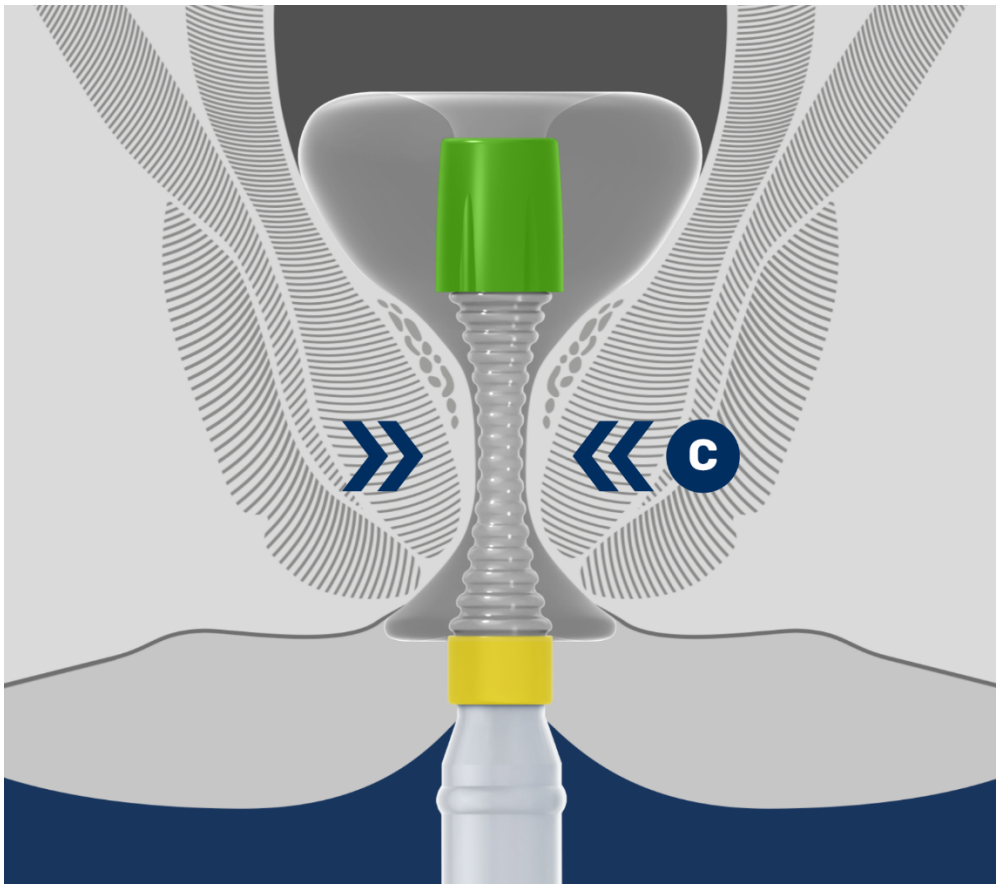
- Hygh-tec follows the respective position of the anal sphincter (C)
- Contracts radially under the force of normal tone from (<40 mmHg) the external anal sphincter (EAS) muscle and does not put undue radial pressure on the anal canal
    - Internal Anal Sphincter (IAS) is responsible for >70% of resting anal pressure as it generates anal tone[1,2]
    - External Anal Sphincter (EAS) – responsible for <30% of resting anal pressure and surrounds IAS into the anal canal when sphincter tone increases[1,2]
- 

Figure 2: IAS-EAS Contraction

The normal pressures exerted by the internal and external anal sphincters are as follows:

- **Internal Anal Sphincter (IAS)**: The resting pressure typically ranges from **50 to 100 mmHg**[3]. During contraction, the pressure can increase significantly.
- **External Anal Sphincter (EAS)**: The pressure exerted during a voluntary squeeze can rise to about **120 to 170 mmHg**, which is roughly one and a half times the resting pressure[4].

These pressures are essential for maintaining continence and controlling the release of stool. At rest, both sphincters contract at relatively uniform pressures and the striated components of the ***anal canal form a complete ring*** to exert more uniform pressure[2].

Citations:

1. Keef, K.D. and C.A. Cobine, *Control of Motility in the Internal Anal Sphincter.* J Neurogastroenterol Motil, 2019. **25**(2): p. 189-204.
2. Schizas, A.M., et al., *Synchronized functional anal sphincter assessment: maximizing the potential of anal vector manometry and 3-D anal endosonography.* Neurogastroenterol Motil, 2016. **28**(7): p. 1075-82.
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